510(k) Summary

Date of Summary:	July 29, 2013
Applicant:	Caldera Medical, Inc. 5171 Clareton Drive Agoura Hills, CA 91301 P (818) 879-6555 F (818) 879-6556
Contact:	Vicki Gail Quality and Operations Manager P (818) 483-7602 F (818) 736-9083 E vgail@calderamedical.com
Device Name:	Surgical Mesh (878.3300)
Device Class:	Class II, Product Code OTN, 21 CFR 878.3300, Gynecologic, For Stress Urinary Incontinence, Female, Obstetrics/Gynecology Panel
Trade Name:	Desara Mesh
Common Name:	Surgical Mesh
Predicate Device:	Desara Mesh , K101169

Description of Device:

The Desara Mesh is a sterile, single-use pubourethral sling used to provide support in the pelvic region to treat stress urinary incontinence, mixed incontinence, and vaginal vault prolapse. The device is manufactured out of a monofilament polypropylene yarn, which is knitted into a mesh. The device has integral sleeves, tips and sutures to assist the surgeon in placement of the device. The sleeves, tips and sutures are removed after placement of the device.

Intended Use of Device:

The Desara Mesh is intended to be used in females to position a mesh for the treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence, resulting from urethral hypermobility or intrinsic sphincter deficiency.

Summary of Technological Characteristics

The Desara Mesh contains a change in the tip resin material only. The Desara Mesh and the predicate mesh are comprised of the same knit pattern, mesh and other component materials. The Desara Mesh is the same shape and size as the predicate mesh. The Desara Mesh has the same intended use and does not change the fundamental scientific technology of the predicate device.

Performance Summary

The Desara Mesh is produced from the same mesh material as the predicate device, Desara Mesh, #K101169, also a product of Caldera Medical. The mesh material has passed all testing requirements for biocompatibility, performance, shelf life and sterilization. The Desara Mesh material has been subjected to cadaver labs, bench and validation testing and has passed all testing criteria.

Summary of Substantial Equivalence

The Desara Mesh is safe and effective for its intended use and is substantially equivalent to the predicate device, Desara Mesh, K101169, also a product of Caldera Medical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 13, 2013

Caldera Medical, Inc.
% Vicki Gail
Quality and Operations Manager
5171 Clareton Drive
Agoura Hills, CA 91301

Re: K112609
Trade/Device Name: Desara® Mesh
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated (Date on orig SE ltr): September 7, 2011
Received (Date on orig SE ltr): September 8, 2011

Dear Vicki Gail,

This letter corrects our substantially equivalent letter of September 30, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112609

Device Name: Desara® Mesh

Indications for Use:

The Desara® Mesh is intended to be used in females to position a mesh for the treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.

Prescription Use [X] (21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use [ ] (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S